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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/090,173

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EXAMINER

DIXON, ANNETTE FREDRICKA

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/090,173	<b>Applicant(s)</b> GUNARATNAM ET AL.	
	<b>Examiner</b> Annette F. Dixon	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 33-35, 39, 62, 63 and 71-106 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 62, 63, 97 and 98 is/are allowed.
- 6) ☒ Claim(s) 33-35, 39, 71-95 and 99-106 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

1. This Office action is in response to the Appeal Brief filed on September 10, 2008. Examiner acknowledges claims 33-35, 39, 62, 63, and 71-106 are pending in this application.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 39, 80-86, and 99-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urso (5,069,205) in view of Haines et al. (5,996,192).

As to Claims 39 and 99, Urso discloses a respiratory mask and head gear combination (Figure 1) comprising a respiratory mask (12) having a rigid mask frame (Column 2, Lines 50-52, and a headgear (the combination of elements 28 and 30) for securing said mask (12) on a patient (Figure 1), said headgear including at least one attachment strap (39), said mask frame (12) having secured thereto a rigid first connector portion (22) further comprising a second connector portion (42) adapted for reliable mating with said first connector portion, said second connector being connected to said attachment strap (39), wherein said first (22) and second connector portions (42) form a press—release connection between said mask frame (12, Column 2, Lines 50-52) and said strap (39). Regarding the rigidity of the first connector portion, Urso

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discloses the first connector may be integrally connected to the face piece (Column 2, Lines 66-67). Further, the forces exerted on the ability of the first connector to attach to the second connector would require a material of sufficient stiffness to ensure securement of the device on the head of the user. Yet Urso does not expressly disclose the first connector to be female and secured to the mask frame, and the second connector to be male having a cantilever member from a leading end portion and said male connector being lockable with the female connector. However, at the time the invention was made the arrangement of the male and female connectors was known as well as the cantilever member on the male connector. Regarding the arrangement of the male and female connectors, it would have been obvious to one having ordinary skill in the art at the time the invention was made to arrange the male and female connectors, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. Regarding the cantilever member on the male connector, Haines discloses a buckle (10) for coupling two elements together, wherein the male connector has a cantilever members (32 and 44) wherein the cantilever members are locked with the female connector (Figures 9 and 10). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an alternative coupling means such as a buckle, as taught by Haines for the purpose of securing the mask to the user's face.

As to Claims 86 and 100, Urso discloses a female connector (42) secured to the mask frame (12) to permit the male connector portion (22) to be connected to and disconnected from the female connector portion (42) in a single hand operation. (Figure

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1). Regarding the orientation of the male and female connectors, it would have been obvious to one having ordinary skill in the art at the time the invention was made to arrange the male and female connectors, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Regarding the single hand operation, the ability of the mask device to be removed by a single hand is a function of the patient's hand and finger flexibility and dexterity.

As to Claims 80 and 101, Urso discloses the mask frame (12) has a front wall portion having a circular gas inlet aperture (18) for connecting a gas delivery conduit (Column 2, Lines 55-60). Further, Urso discloses a side wall portion (the location at which seal 16 is located) and a base portion (the area below the aperture, 18).

As to Claims 85 and 102, Urso discloses a female connector, yet does not expressly disclose the orientation of the female connector on the front wall portion. Regarding the orientation of the male and female connectors, it would have been obvious to one having ordinary skill in the art at the time the invention was made to arrange the male and female connectors, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

As to Claims 81 and 103, Urso discloses a rim (the end of the lens, 14) wherein a cushion (16) is applied.

As to Claims 84 and 104, Urso discloses the cushion (16) above the head of the user is a forehead support.

As to Claims 82, 83, 105 and 106, the system of Urso/Haines includes a connector with a lug. Specifically, Haines teaches a lug (46) with a wedge profile to engage the socket of the female connector (Figures 9 and 10).

4. Claims 33-35 and 87-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urso (5,069,205) in view of Kasai (4,802,262).

As to Claims 33 and 87, Urso discloses a respiratory mask and head gear combination (Figure 1) comprising a respiratory mask (12) having a mask frame (Column 2, Lines 50-52, and a headgear (the combination of elements 28 and 30) for securing said mask (12) on a patient (Figure 1), said headgear including at least one attachment strap (39), said mask frame (12) having secured thereto a female connector portion (22) further comprising a male connector portion (42) adapted for reliable mating with said female connector portion, said male connector being connected to said attachment strap (39), wherein said female (22) and male connector portions (42) form a press—release connection between said mask frame (12, Column 2, Lines 50-52) and said strap (39). Yet Urso does not expressly disclose the particulars of the male connector having a trailing portion, a pair of side portions, a cross bar, a leading portion, a cantilevered member, and locking element extending outwardly from the cantilevered member. However, at the time the invention was made the arrangement of the male connector was known. Specifically, Kasai discloses a male connector (Figure 6) having a trailing portion (26) with a pair of side portions (36 and 37) with a cross bar (28) extending transversely there between, a leading portion (27) including a cantilever (30)

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extending from the trailing portion (26) with a cross piece (31) and a locking element (32) extending from the cantilever (30) for the purpose of providing a simple and reliable coupling. (Column 1, Lines 30-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an alternative coupling means such as a buckle, as taught by Kasai for the purpose of securing the mask to the user's face.

As to Claim 34, Urso discloses the mask frame (12) has a front wall portion having a circular gas inlet aperture (18) for connecting a gas delivery conduit (Column 2, Lines 55-60). Further, Urso discloses a side wall portion (the location at which seal 16 is located) and a base portion (the area below the aperture, 18).

As to Claim 35, Urso discloses a rim (the end of the lens, 14) wherein a cushion (16) is applied.

As to Claims 71 and 88, the space between the cross bar (28) and element 26 provides a groove on the top of the coupling as seen in Figure 7,

As to Claims 72 and 89, the combination of the prior art references teaches a single locking lug (32), yet does not teach a plurality of locking lugs. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a plurality of locking lugs, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

As to Claims 73 and 90, as seen in Figure 7, the locking lug (32) is in a wedge shape.

As to Claims 74 and 91, as seen in Figure 7, there is a ridge (34) formed on the cantilever member.

As to Claims 75, 92 and 93, the combination of the prior art references discloses a ridge (34), yet does not expressly disclose the ridge's shape. However, a change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47.

As to Claims 76 and 94, Kasai discloses the cross bar (28) receives the strap (Column 3, Line 20). Regarding the size of the aperture, a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

As to Claims 77, Urso discloses the cushion (16) above the head of the user is a forehead support.

As to Claims 78 and 79, Urso discloses a female connector (42) secured to the mask frame (12) to permit the male connector portion (22) to be connected to and disconnected from the female connector portion (42) in a single hand operation. (Figure 1). Regarding the orientation of the male and female connectors, it would have been obvious to one having ordinary skill in the art at the time the invention was made to arrange the male and female connectors, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. Regarding the single hand operation, the ability of the mask device to be removed by a single hand is a function of the patient's hand and finger flexibility and dexterity.

As to Claim 95, Kasai discloses the leading side (27) and the trailing side (26), yet does not expressly disclose the shape of the sides. However, a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

As to Claim 96, Kasai discloses the ridge (34), yet does not expressly disclose the size of the ridge. However, a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

#### ***Allowable Subject Matter***

5. Claims 62, 63, 97 and 98 are allowed over the prior art made of record.

#### ***Response to Arguments***

6. Applicant's arguments with respect to claims 33-35, 39, 62, 63, and 71-106 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Klein (5,396,881) discloses an additional respiratory mask having a coupling mechanism to connect the straps to the mask frame. Fudaki (5,263,234) and Ikeda (4,928,364) discloses additional coupling mechanisms.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon  
Examiner  
Art Unit 3771

/Annette F Dixon/  
Examiner, Art Unit 3771

/Justine R Yu/  
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